REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official action.

Claims 17-33 are pending in the present application. Support for claims 17-33 may be found in original claims 1-16 and in the present specification at page 3, line 22 to page 4, line 16; page 5, lines 12-23; and page 6, lines 25-30.

In the outstanding official Action, claims 7-16 were rejected under 35 USC §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed.

In imposing the rejection, the Official Action alleged that the term "the reagent solution" lacked antecedent basis. In addition, the Official Action alleged that the claims recite several possible solutions which might be "the reagent solution". However, as noted above, claim 7 has been canceled. Applicants believe that claims 17-33 have been rewritten in a manner so that the term "the reagent solution" has been provided antecedent basis and is definite to one skilled in the art.

Claim 8 was rejected for reciting the term "used for comparative purposes". The new claims have been drafted in a manner so that this phrase no longer appears in the claims.

Claims 9, 10, 12 and 13 were rejected for reciting the term "compared with respect to their ability to resist enzymatic degradation". In imposing the rejection, the Official Action alleged that the claims did not set forth the criteria for the comparison and that it was not clear what actual process steps were required. Claims 17-33 have been drafted in a manner so that this phrase no longer appears in the claims. While claims 22-33 are directed to a method for predicting the enzymatic degradation resistance of a starch sample in vivo, applicants note that claims 22-33 do recite that a starch sample is compared with a standard or blank sample to provide a comparison. As a result, applicants believe that new claims 17-33 are definite to one skilled in the art.

Claim 11 was rejected for reciting the terms "used to predict the enzymatic degradation profile of starch *in vivo*" and "degradation profile". As to the phrase "used to predict the enzymatic degradation profile of starch *in vivo*", applicants believe that the claims have been drafted in a manner so as to recite process steps that explain the process steps involved in practicing the claimed method.

As to the term "degradation profile", applicants believe that this term is definite to one of ordinary skill in the art. Indeed, the Examiner's attention is respectfully

directed to page 8, lines 26-30, wherein this phrase is is expalined.

Claims 1, 9, 10, 12, 13, 15 and 16 were rejected under 35 USC §102(b) as allegedly being anticipated by RING et al. Claims 1-3 and 8-16 were rejected under 35 USC §103(a) as allegedly being unpatentable over RING et al. These rejections are respectfully traversed.

In imposing the rejection, the Official Action alleges that RING et al. disclose the enzymatic digestion of starch in the colorimetric assessment of an enzymatic digestion. However, while the RING et al. article relates to how the physico-chemical form of starch affects both the rate and the extent of its hydrolysis by an amylolytic enzyme, RING et al. hope to identify the corresponding differences in the digestibility of starch in a food product. In doing so, RING et al. hope to develop a food product with improved nutritional characteristics (See RING et al. pg. 108). Thus, RING et al. is not interested in developing an analytical method for determining the resistance to the degradation of a starch product to predict the enzymatic degradation of a starch product in vivo.

In contrast to RING et al., the present invention is directed to finding not only a measure of the digestibility of starch *in vitro*, but to find a method that accurately predicts

the digestibility *in vivo*, and the effects on the blood sugar level in a patient ingesting such a composition.

The method according to RING et al. is a strictly quantitative method, wherein the entire amount of available starch is hydrolyzed. The claimed method on the other hand represents a qualitative analysis of the degradation properties. The total amount of starch is accurately known, as it is the active component in the composition, it is the *in vivo* digestibility that is evaluated.

Moreover, in RING et al., the starch is gelatinized and, prior to enzyme hydrolysis, the gel sample disrupted in a tissue homogenizer. This stands in contrast to the claimed method. There is no gelatinization step or homogenization step disclosed. Instead, the product is treated very gently, in conditions resembling those found in the human gastrointestinal tract.

As RING et al. requires a heat step, it is clear that the method according to RING et al. would not be useful for prediction, validation and quality control purposes. Indeed, if one were to use the RING et al. method to compare two different pharmaceutical formulations of granulated native starch, the RING et al. method would only show that these compositions contain an equal amount of starch. Thus, at best, it is questionable if

RING could reveal any useful, comparative information about their degradation resistance.

The claimed invention also recites a buffer which has a neutral pH and contains about 0.01 M chloride ion. An enzyme is also added in an amount approximately 15,000 IU/4.0 g starch. Applicants note that RING et al. fail to disclose or suggest the recited chloride concentration or enzyme level. Indeed, as RING et al. fail to disclose or suggest the chloride ion concentration or claimed enzyme levels, applicants believe that RING et al. fail to disclose or suggest the claimed invention.

Thus, in view of the above, applicants believe that RING et al. fail to anticipate or render obvious the claimed invention.

Claims 1-16 were rejected under 35 USC §103(a) as allegedly being unpatentable over RING et al. in view of BERNFELD. This rejection is respectfully traversed.

The BERNFELD publication has a publication date of 1955 and relates to an assay method for α-amylase. However, BERNFELD fails to disclose or suggest the claimed conditions for practicing the method for the present invention as identified above. BERNFELD does not disclose or suggest a method for the analysis of the degradation resistance of native starch to predict the enzymatic degradation behaviour of starch in vivo. Indeed, the BERNFELD reference does not disclose a comparative

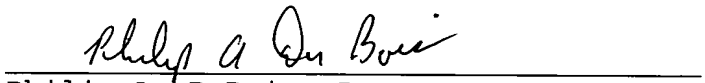
process step or the claimed chloride concentration or enzyme levels. As a result, applicants believe that BERNFELD fails to remedy the deficiencies of RING et al. As a result, applicants request that the obviousness rejection based on RING et al. in view of BERNFELD be withdrawn.

In view of the present amendment and the foregoing remarks, therefore, applicants believe that the present application has been placed in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON



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